

### **REMARKS**

Claims 2-4, 6, 10-13 and 25-38 were previously pending in this application. By this amendment, no claims have been canceled, claims 26 and 35-38 have been amended, and new claims 39-43 have been added. As a result, claims 2-4, 6, 10-13 and 25-43 are pending for examination with claims 25, 26 and 39 being independent claims. No new matter has been added. Applicant respectfully requests reconsideration in view of these amendments and the following arguments.

Applicant would like to thank Examiner Gray for his courtesies during a telephone interview with Larry Green and Shannon Pratt on June 17, 2008. The rejections in view of Uber (U.S. Patent No. 5,843,037) as well as the objection to claim 26 were discussed. No agreement was reached. The substance of the discussion is incorporated into the following remarks.

#### ***Claim Objections***

In the Office Action dated January 29, 2008, claims 26 and 34-38 were objected to as being indefinite. In particular, the Office Action stated that the limitation “a predetermined maximum pressure of the downstream segment in the absence of injection” is unclear and not descriptive.

In response to this objection, claim 26 has been amended to clarify that the opening pressure of the first occlusion device is greater than a venous pressure of the patient which corresponds to a maximum pressure of the downstream segment in the absence of injection. This amendment language was discussed during the telephone interview and the Examiner preliminarily indicated that this language would likely overcome the claim objection. Support for this amendment may be found at least on page 3, lines 20-21 and page 10, line 4.

In the Office Action, claims 34-38 were objected to as being indefinite and in particular the Office Action inquired as to the meaning of “bars”. The Office Action stated that the Examiner assumes that the Applicant means “Bar” as a unit of pressure equal to  $10^5$  Pascal. The Examiner is informed that this assumption is correct.

In response to this objection, claims 34-38 have been amended to capitalize the term “Bar”. Accordingly, withdrawal of these objections is respectfully requested.

***Rejections Under 35 U.S.C. §102***

In the Office Action dated January 29, 2008, independent claims 25 and 26 were both rejected under 35 U.S.C. §102(b) as being anticipated by Uber (U.S. Patent No. 5,843,037). Applicant respectfully traverses this rejection.

Independent Claim 25

Independent claim 25 is directed to a method for injecting liquid under pressure to a patient. The method includes the step of providing liquid under pressure to a patient through a length of tubing, where the tubing includes a pressurizing system, a first occlusion system and a regulation system located upstream from the first occlusion system. The first occlusion system and the regulation system define an intermediate segment having an intermediate pressure and the tubing also includes a segment downstream of the first occlusion system having a downstream pressure. Due to the action of the pressurizing system, there is a positive pressure during the injection in the intermediate segment and the downstream segment.

The method further includes, when injection to the patient is desired to be stopped, closing the regulation system and the first occlusion system *in such a manner that part of said positive pressure is maintained in the intermediate segment, while the pressure in the downstream segment is not maintained at such positive pressure*, at least until the patient is disconnected from the tubing. There is no teaching or suggestion in Uber of this recitation.

Uber is directed to a device for delivering a liquid into a patient. The Uber device includes a metering pump 12, a static mixer 20, a pressurization pump 25 and a rotary switch 27 which can distribute the liquid between multiple patients through patient hookups 30, 31, 32. The Office Action appears to refer to the metering pump 12, the static mixer 20 and reference numeral "21" (shown in FIG. 1 but not mentioned in the Uber specification) as the equivalent of "valve/ pump regulation system elements". The Office Action also referred to the rotary valve 27 as being equivalent to the "occlusion system" and the supply conduit 26 (which runs between the pressurization pump 25 and the rotary switch 27) as being equivalent to the "intermediate segment".

The Office Action stated that "the claim limitations of the intermediate segment having an intermediate pressure greater than the downstream segment would be evident in operation of the

system”. The Office Action further stated that this “pressure difference would be evident due to the fact that the liquid flows to the patient and not upstream into the reservoir, besides the overall nature of fluid dynamics.” The Office Action also stated “that Uber discloses all the steps in the method (1. providing liquid, 2. closing the regulation system, 3. closing the occlusion system) and these steps are carried out on a structural apparatus similar to the claimed structural apparatus (tubes with regulation system and occlusion system)”.

As an initial matter it is noted that independent claim 25 is directed to a method, not an apparatus, so that even if an apparatus similar to the Applicant’s apparatus is disclosed in Uber (which Applicant does not concede), that is not indicative of whether Uber teaches or suggests the method recited in independent claim 25.

Most significantly, Uber does not teach or suggest all of the limitations recited in the method of claim 25. In particular, Uber does not teach or suggest that once the injection to the patient is desired to be stopped, closing the regulation system and the first occlusion system *in such a manner that part of said positive pressure is maintained in the intermediate segment, while the pressure in the downstream segment is not maintained at such positive pressure*, at least until the patient is disconnected from the tubing.

The Office Action stated that this limitation in claim 25 is a functional limitation and is not a positive limitation, and thus it only requires the ability to so perform. The Examiner does not appear to be giving this limitation any patentable weight. While such functional limitations may or may not be entitled to weight in an apparatus claim, such limitations are what define a method claim, such as claim 25, and are a positive limitation which should be given patentable weight. The claim limitation of maintaining the positive pressure in the intermediate segment while the positive pressure in the downstream segment is not maintained once injection is desired to be stopped is not “evident” from Uber because it is not taught to occur in the operation of the Uber system. In fact, Uber teaches that it does not occur.

The Examiner’s attention is directed specifically to Column 4, Lines 55-60 of Uber where it is stated that: “a peristaltic system while effective is not sufficient to prevent cross-contamination if turned backwards, either by operator action or by back pressure, for example.” Uber goes on to state that in order to prevent backflow (the claimed method of the present invention), “there should

be back flow prevention means in the line, or preferably in the peristaltic mechanism itself.” (Column 4, lines 58-60). In Columns 4 and 5, Uber describes what he means by backflow prevention means. Each of these systems involves a very complicated apparatus, in addition to the apparatus that the Examiner states is found in the present invention, to prevent such backflow or cross-contamination. For example, in Fig. 8, a system is described in which the fluid path splits in two parts. Fluid flows into inlet 6 of chamber 1, and its outlet 7 is blocked so that the chamber expands and drives the pressure plate 3 against the chamber 2. This drives the fluid out of chamber 2 and onto the patient. (Column 4, lines 61-67). Another solution to this problem is disclosed in Fig. 10 and Column 5, lines 13-39. In Figs. 6 and 7, an air gap is disclosed as a blocking means to preclude cross-contamination. (Column 5, lines 61-65). There would be no need for an additional backflow prevention means in the Uber apparatus if the Uber system operated as recited in claim 25 or if the claimed method were “evident” from the operation of Uber. If, in the operation of Uber, the positive pressure in the intermediate segment was maintained while the pressure in the downstream segment was not maintained once injection is desired to be stopped, none of these systems proposed by Uber would be necessary. Any such systems would be redundant. Moreover, the solution to the problem of contamination as set forth in the claims herein is clearly non-obvious over Uber. If Uber operated in the manner claimed, Uber would not use the complicated systems proposed by Uber. Applicant has solved the same problem solved by Uber but in a simpler and more elegant fashion.

For at least these reasons, independent claim 25 is patentable over Uber.

#### Independent Claim 26

As mentioned above, Applicant has amended independent claim 26 to more clearly distinguish over Uber. Independent claim 26 is also directed to a method for injecting liquid under pressure to a patient. The method includes providing liquid under pressure to a patient through a length of tubing, where the tubing includes a pressurizing system, a first occlusion system and a regulation system located upstream from the first occlusion system. The first occlusion system and the regulation system define an intermediate segment having an intermediate pressure and the tubing also includes a segment downstream of the first occlusion system having a downstream

pressure. Due to the action of the pressurizing system, there is a positive pressure during the injection in the intermediate segment and the downstream segment.

As amended, the method further includes, when injection to the patient is desired to be stopped, closing the regulation system and the first occlusion system *in such a manner that the first occlusion system closes when the pressure in the intermediate segment falls below an opening pressure of the first occlusion system, where the opening pressure of the first occlusion system is greater than a venous pressure of the patient which corresponds to a maximum pressure of the downstream segment in the absence of injection, so that part of said positive pressure is maintained in the intermediate segment, while the pressure in the downstream segment is not maintained at such positive pressure*, at least until the patient is disconnected from the tubing, in order to direct leakage of fluid from the first occlusion system to the patient. There is no teaching or suggestion in Uber of this recitation.

Uber is directed to a device for delivering a liquid into a patient. As discussed above with respect to claim 25, there is no teaching or suggestion in Uber for maintaining part of the positive pressure in the intermediate segment while the pressure in the downstream segment is not maintained at such positive pressure at least until the patient is disconnected from the tubing in order to direct leakage of fluid from the first occlusion system to the patient.

Additionally, there is no teaching or suggestion in Uber for the first occlusion system to close when the pressure in the intermediate segment falls below a venous pressure of the patient which corresponds to a maximum pressure of the downstream segment in the absence of injection. This method simply is not taught in Uber. In fact, as discussed above, Uber teaches that these claimed steps do not occur in the operation of the Uber device, because backflow is stated to be a problem in the operation of the Uber device.

For at least these reasons, independent claim 26 is patentable over Uber.

### ***Rejections Under 35 U.S.C. §103***

In the Office Action dated January 29, 2008, claims 2-4, 6, 10-13 and 27-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Uber in view of Lichtenstein (U.S. Patent No. 4,464,172).

Without acceding to the propriety of these rejections, claims 2-4, 6, 10-13 and 27-34 depend on either independent claim 25 or 26, and are thus patentable for at least the same reasons discussed above.

Accordingly, the rejections of these claims should be withdrawn.

### ***New Claims***

Applicant has added new independent claim 39 and dependent claims 40-43 to further define the invention. Claim 39 was proposed to the Examiner and discussed during the interview. Support for the new claims may be found at least on page 2, lines 2-11, page 3, lines 3-11, page 5, lines 12-24, page 6, lines 10-16.

New independent claim 39 is directed to a method for injecting liquid under pressure to a patient. The method includes providing liquid under pressure to a patient through a length of tubing, where the tubing includes a pressurizing system, a first occlusion system and a regulation system located upstream from the first occlusion system. The first occlusion system and the regulation system define an intermediate segment having an intermediate pressure and the tubing also includes a segment downstream of the first occlusion system having a downstream pressure. The method also includes creating a positive pressure in the intermediate segment and the downstream segment with the pressurizing system during injecting of a liquid to a patient, and preventing backflow away from the patient and into the intermediate segment when injection to a patient is desired to be stopped, by maintaining a greater pressure in the intermediate segment than in the downstream segment, at least until the patient is disconnected from the tubing.

As discussed above and during the telephone interview, Uber fails to teach or suggest the step of *preventing backflow away from the patient and into the intermediate segment when injection to a patient is desired to be stopped, by maintaining a greater pressure in the intermediate segment than in the downstream segment, at least until the patient is disconnected from the tubing*. As noted, there is no suggestion whatsoever of this recitation in Uber. Moreover, the fact that backflow is a problem in Uber and must be corrected not using this method, but using other very complicated apparatus, tells one of skill in the art that Uber is not operated in the manner claimed. If it were,

backflow would not be a problem and the extra apparatus would not be required. The use of the extra apparatus actually teaches away from Applicant's elegant solution to the backflow problem.

New claims 40-43 depend from new claim 39 and are patentable for at least the same reasons as claim 34.

### CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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